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Diet and Food Supplements : Effects on Body with Analysis of Legal Aspects

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Abstract

In the United States, many adults and kids use one or more vitamins or other nutritional supplements. Dietary supplements can also include minerals, herbs, other botanicals, amino acids, enzymes, and a variety of other components in addition to vitamins. Dietary supplements are available in many different formats, such as pills, capsules, candies, powders, beverages, and energy bars. Vitamins D and B12, minerals like calcium and iron, herbs like echinacea and garlic, and goods like glucosamine, probiotics, and fish oils are all common supplements. Over 70% of Americans consume nutritional supplements on a daily basis, and the $28 billion global market for these products is booming. However, supplements do not require FDA registration or approval prior to production or sale, unlike either foods or medications. The Dietary Supplement Health and Education Act of 1994 (DSHEA) limits FDA's monitoring to post-marketing adverse report analysis. Despite widespread use, there is little proof that supplements or nutraceuticals improve the health of adults who eat healthily. However, a few of these products have the capacity to cause substantial toxicity. Additionally, it is uncommon for individuals to

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tell their doctors they use supplements. Consequently, there is a high chance of negative drug-supplement interactions.

Keywords : Diet and Food Supplements, Food Supplements, Legal Aspects of Food Supplements

Introduction

In current era, there is huge trend and practices towards consumption of dietary and food supplements specifically with the young generation. In addition, the sports persons consume the supplements to escalate their performance. There are assorted aspects in terms of effects on body as well as legal points which are addressed here. The current food laws in India are outlined in the (Indian) Food Safety And Standards Act, 2006 (FSS Act). Section 22 of the FSS Act imposes an embargo on the production, distribution, sale, and import of novel foods, genetically modified foods, irradiated foods, organic foods, foods for special dietary purposes, functional foods, neutraceuticals, health supplements, proprietary foods, and other foods that violate the embargo. Prior to the passage of the FSS Act, manufacturers were required to abide by the Prevention of Food Adulteration Act of 1954 (PFAA) and its implementing rules.

Given the smudgy demarcation between "drugs/medicines" and "nutritional supplements," one potential risk for the production and sale of food/health supplements like "dietary food supplements," "food supplements," "nutritional supplements," and "health supplements" is their classification as either "food" or "drugs." Almost all nutritional supplement ingredients, identified by various nomenclatures, comprise substances that may be classified as both medications and food supplements.

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Figure 1 : Global Market of Dietary Supplements

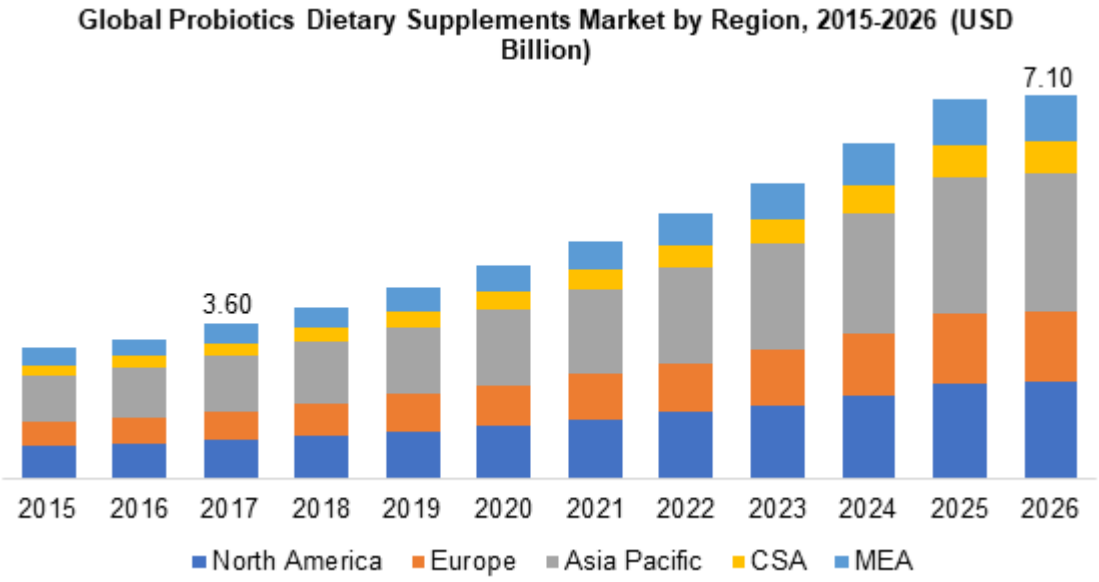

Figure 2 : Global Aspects and Market Size of Dietary Supplements

To determine whether a specific manufacturer or seller of the aforementioned products would become eligible for mandatory regularisation under the FSS Act, the classification of "Dietary food supplement," "Food supplements," "Nutritional

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supplements," and "Health supplements" becomes crucial. This is because the new Rules, 1 FOOD SAFETY AND STANDARDS (LICENSING AND REGISTRATION OF FOOD BUSINESSES) REGULATIONS, 2011, or "FSS Regulations," created under the FSS Act, also

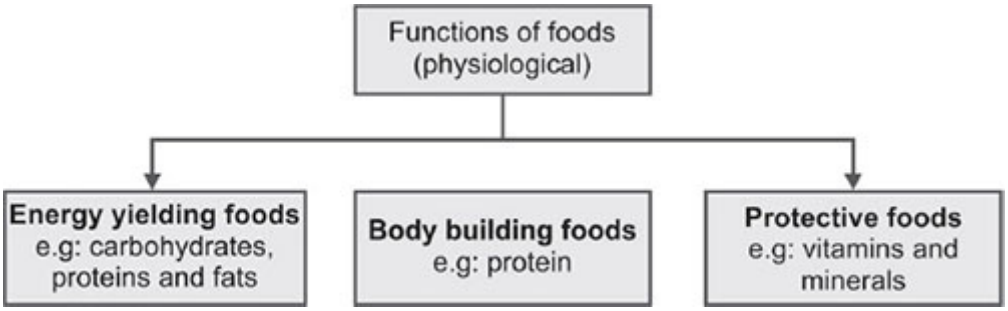

Figure 3 : Physiological Aspects

Effectiveness

Some dietary supplements can help you get adequate amounts of essential nutrients if you don't eat a nutritious variety of foods. However, supplements can't take the place of the variety of foods that are important to a healthy diet. To learn more about what makes a healthy diet, the Dietary Guidelines for Americans and MyPlate are good sources of information.

Some dietary supplements can improve overall health and help manage some health conditions. For example:

- Calcium and vitamin D help keep bones strong and reduce bone loss.
- Folic acid decreases the risk of certain birth defects.
- Omega-3 fatty acids from fish oils might help some people with heart disease.

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- A combination of vitamins C and E, zinc, copper, lutein, and zeaxanthin (known as AREDS) may slow down further vision loss in people with age-related macular degeneration (AMD).

Many other supplements need more study to determine if they have value. The U.S. Food and Drug Administration (FDA) does not determine whether dietary supplements are effective before they are marketed.

Table 1 : Key herb-drug pharmacokinetic interactions

Enzyme	**Dose (day^{-1}), duration**	**Botanical**	**Probe;[a] effect[b]**
CYP3A4	600 mg, 12 d	Goldenseal	CsA; inhibition
	1600 mg, 8 d	Echinacea	MDZ; induction of hepatic 3A4, inhibition of intestinal 3A4
	Various	St. John's Wort	Various; induction
	2000 mg, 28 d	Ginseng	MDZ; induction
	800 mg, 4 wk	Green Tea extract	Buspirone; inhibition
CYP2D6	2700 mg, 28 d		Debrisoquine; inhibition
	3210 mg, 14 d	Goldenseal	Debrisoquine; inhibition
CYP1A2	1600 mg, 8 d		Caffeine; inhibition
	1600 mg, 28 d		Caffeine; inhibition ($p = 0.07$, not clinically relevant)
	1000–4000 mg, >6 years (analysis following 30-day	Echinacea	Caffeine; inhibition

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	cessation)		
CYP2E1	1500 g, 28 d		CZX; inhibition
	2000 mg, 28 d	Kava kava	CZX; inhibition
CYP2C19	280 mg, 12 d		OPZ; induction (genotype effect)
	900 mg, 14 d	Garlic	S-mephenytoin; induction (genotype effect)
CYP2C9	420 mg, 14 d	Kava kava	Losartan; inhibition (genotype effect)
	900 mg, 14 d		Losartan; inhibition
	1600 mg, 8 d	Ginkgo biloba	Tolbutamide; inhibition
OATP1A2	637 mg, 14 d	St. John's Wort	Nadolol; inhibition
P-glycoprotein	1200 mg, 21 d		Saquinavir; induction
	360 mg, 14 d	Milk thistle	Talinolol; inhibition
	2000–4000 mg, 14 d	Goldenseal	Digoxin; induction

[a]MDZ: midazolam; CZX: chlorzoxazone; OPZ: omeprazole; CsA: cyclosporin A.

[b]Genotype effect: Effect seen in high-efficiency metabolizers but not in low-efficiency.

It is crucial to note that a variety of goods are being marketed as health/food supplements in the Indian market and claim to have high levels of vitamins and minerals. Multivitamin pills and other goods containing nutrients are also being marketed as medications, with the necessary approval from the drug regulators.

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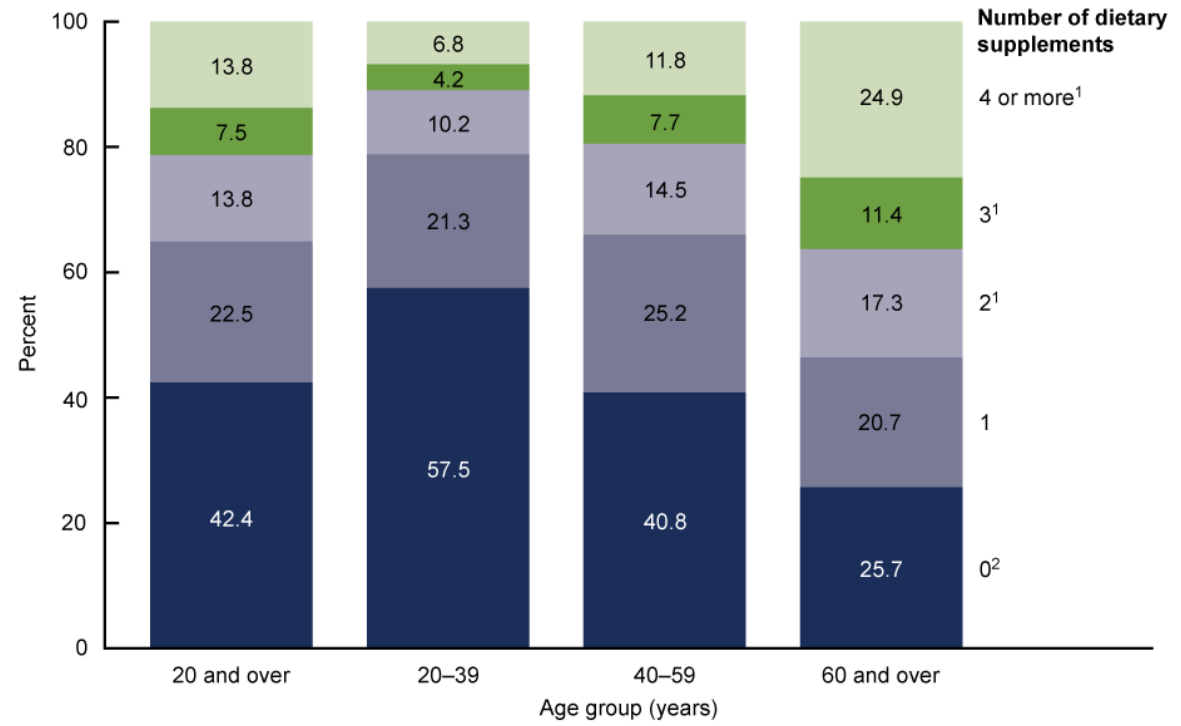

gnificant linear increasing trend with age.
gnificant linear decreasing trend with age.
)TE: Access data table for Figure 2 at: https://www.cdc.gov/nchs/data/databriefs/db399-tables-508.pdf#2.
)URCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Figure 4 : Consumption Patterns

The producers and traders of food supplements may be at danger of punishment in the event of improper classification. This confusion, or if it can be stated that the manufacturers took a liberty to escape the strictures of drug laws under the guise of food safety rules, acquires importance. The line separating food from health supplements from pharmaceuticals is sometimes blurry, especially when nutritional value and vitamin content are specifically highlighted for a variety of commercial purposes, making the categorization very arbitrary. Additionally, there isn't judicial agreement on this issue. There is no precise statutory or judicial standard that can be used to decide this issue. As a result, whether a health and nutritional supplement

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is classified as a "food supplement" or a "drug" will depend on an investigation of its ingredients and other components, as well as the authorities' subjective judgement.

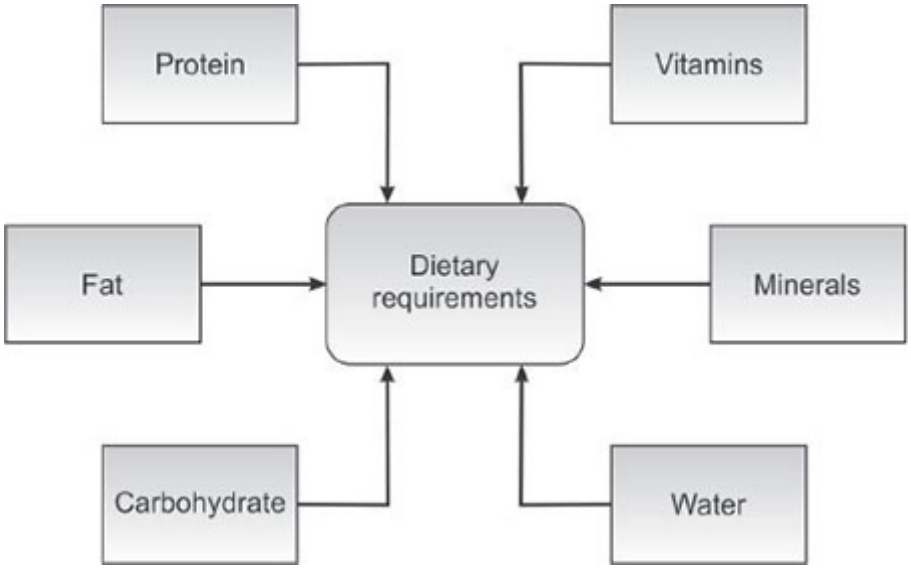

Figure 5 : Key Points with Dietary Requirements

A product taken orally that comprises a dietary element and/or a novel dietary ingredient designed to augment the diet may be referred to as a dietary supplement. These items may contain vitamins, minerals, herbs, or other botanicals as nutritional components. things include enzymes, organ tissues, glandular substances, and amino acids.

Legal Perspectives

However, despite the legislative mandate, no rules under Section 22 of the FSS Act have been notified till date. The explanation of Section 22 of the FSS Act defines "foods for special dietary uses or functional foods or neutraceuticals or health supplements" in the following terms:

(a) foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:-

(i) plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;

(ii) minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);

(iii) substances from animal origin;

(iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake; and

(b)

(i) a product that is labelled as a "Food for special dietary uses or functional foods or neutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;

(ii) such product does not include a drug as defined in clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made there under;

(iii) does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;

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(iv) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;

From the above it is clear that under the present Indian law, no person can manufacture, distribute, sell or import any foods for special dietary uses or functional foods or neutraceuticals or health supplements, unless in accordance with the provisions of the FSS Act or FSS Regulations made there under.

It is pertinent to point out that the draft regulations in this regard have been prepared by the Ministry of Health and Family Welfare in exercise of power conferred under Section 22 and 92 of the FSS Act. These draft regulations have elaborately defined the word "health supplements" as under:

'Health Supplements' can be explained as foods which are intended to supplement the normal diet of a person, and which are concentrated sources of one or more nutrients, like minerals, vitamins, proteins, metals or their compounds, amino acids or enzymes, other dietary substances, plants or botanicals , substances from animal origin or other similar substances with known and established nutritional or physiological effect, and which are presented as such, wherein the composition of these foodstuffs differ significantly from the composition of ordinary foods of comparable nature, and are offered alone or in combination, but are not drugs as per the Drugs and Cosmetics Act 1940 and Rules made there under.

The said regulations providing the standards for novel food, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food have yet not been notified. Therefore, under the FSS Act, the position of nutrition and supplements products is still vague and ambiguous.

It may be noted that Section 98 of the FSS Act relates to transitory provisions for food standards and states as under:

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"Notwithstanding the repeal of the enactment and Orders specified in the Second Schedule, the standards, safety requirements and other provisions of the Act and the rules and regulations made there under and Orders listed in that Schedule shall continue to be in force and operate till new standards are specified under this Act or rules and regulations made there under....."

It can be argued that due to Section 98 of the FSS Act, and in absence of notified regulations, Rule 37A of The Prevention of Food Adulteration Rules, 1955 (hereinafter referred as "PFA Rules"), though repealed by the FSS Act, would remain in force and be applicable on manufacture of health supplements food since clause 1 of Rule 37A defines "Proprietary food" as a food which has not been standardized under the PFA Rules, as in the case of health and nutritional supplements which are not defined under the Prevention of Food Adulteration Act, 1954.

Rule 37A of the PFA Rules provides as under:

"37A MANUFACTURE OF PROPRIETARY FOODS:

(1) Proprietary food means a food which has not been standardized under the Prevention of Food Adulteration Rules, 1955.

(2) In addition to the provisions including labeling requirements as prescribed under these rules, all proprietary foods shall also conform to the following requirements:-

(a) the manufacturer of proprietary products shall obtain separate licence for manufacture of each proprietary food products;

Provided that Halwais manufacturing traditional foods like Indian traditional snacks and sweets shall obtain a composite licence;

(b) the name of the food and/or category under which it falls in these rules shall be mentioned on the label;

(c) tobacco and nicotine shall not be used as ingredients in the manufacture of proprietary food products;

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(d) where any food contains any allergenic and / or hypersensitive ingredients as identified under the rules, or any ingredient originating from an allergenic and / or hypersensitive ingredients does not specify the allergenic ingredients / hypersensitive ingredients, such food shall the label declaration as provided under clause (24) of subrule (zzz) of rule 42.

(e) the proprietary food product shall not contain food additives except as provided in the rules for that food and / or category of food.".

From the perusal of above Rule 37A, it is clear that any person manufacturing a product as proprietary food under the PFA Rules has to mandatorily comply with the above requirements.

In the case of Glaxo India Ltd. Vs. State Of Assam And Ors[2], the Gauhati High Court held that wherein after considering the composition and ingredients for preparation of both GLUCON-C and GLUCON-D, it was held that these products as such, cannot at all be called an article of 'food under a misbranded name' and without any hesitation one can come to the conclusion to call these products as 'proprietary food'. It was also held that:

"Since 'proprietary food' cannot be the subject-matter of standards laid down in Appendix 'B', the question of non-conformity of the product 'GLUCON-C and GLUCON-D with standards prescribed under Appendix 'B' under Rule 37A, cannot be considered at all for declaring this articles of food as misbranded."

In the case of Hindustan Lever v. Food Inspector[3], the Supreme Court of India has held that the instant dairy whitener is an article for which no standards has been laid and hence the standard for skimmed milk powder cannot be applied to instant dairy whitener as it contained only partly skimmed milk powder with other ingredients. Therefore the standards of such supplements would be determined based on the facts and circumstances of each case.

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In the case of State of Maharashtra vs Pravin Krishnadas Shah[4] it was held that the said supplements cannot be considered as drugs as:

"It is common knowledge that proteins are a body building substance - a nutrition, while a medicine is a therapeutic substance - essentially connected with healing. In absence of evidence on all aspects it will be difficult to term proteins as a 'medicine'."

The definition of "Drugs" has been elaborated under clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred as "the DCA, 1940") and rules made there under.

Section 3 (b) of the DCA, 1940 provides that "drug" includes:

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board ;

From the bare perusal of above section, it is clear that health or nutritional supplements may be categorized as drugs, because of the very wide definition of

drug as provided in the DCA, 1940. Any "foods for special dietary uses or functional foods or neutraceuticals or health supplements" which falls within the definition of "drugs" under the DCA, 1940, has to be excluded from the applicability of the FSS Act.

For understanding the issue, reliance can also be laid on the verdict of the Kerala High Court in Cadila Pharmaceuticals Ltd. vs. State Of Kerala And Ors.

The High Court in the above case held EC 350 (Vitamin E and Vitamin C capsules) and Cecure (Multi-Vitamin Capsules) manufactured by the petitioner and sold in the market through medical shops as "Dietary Supplements" to fall within the definition of "drug" requiring licence under the Drugs and Cosmetics Act, 1940.

It was also held in the above case that "the definition of 'drug' in the Act clearly specifies that all, substances intended to be used for mitigation or prevention of any disease or disorder in human beings is a drug and further all substances intended for use as components of a drug including empty gelatin capsules is a drug."

In the case of Dr. Reddy's Laboratories Limited vs State Of Kerala, the test for determining "whether a particular supplement should be treated as a medicine?" was laid down as under: "The word medicine means, any substance/chemical which when used in a disease will lead to cure or improvement. The dietary supplement means any substance (usually a food item/ingredient) which helps in maintenance of health.

Conclusion

Food supplements, often known as dietary supplements or nutritional supplements, are intended to provide nutrients that may not be consumed in appropriate amounts. Vitamins, minerals, amino acids, fatty acids, and other substances can be included in food supplements, and they can be given as pills, tablets, capsules, liquid, etc. There are many various dosing and mix options for supplements. However, only a specific

quantity of each vitamin is required for our bodies to operate, thus consuming more of a given nutrient is not always preferable. Some drugs may have negative side effects and become hazardous at excessive dosages. Therefore, only supplements that come with a recommendation for an acceptable daily amount and a warning not to exceed that dose can be marketed lawfully in order to protect the health of customers. Supplements cannot replace a healthy, balanced diet. All the elements required for optimum health should typically be present in a diet that contains plenty of fruits, vegetables, whole grains, enough protein, and healthy fats. The majority of European nations concur that messaging intended for the general public should concentrate on dietary recommendations based on foods. Although supplements are not mentioned in these recommendations, there are some population groups or people who might need advise on supplements even if they follow a healthy, balanced diet, such as women of childbearing age or people taking particular drugs. Not everyone is able to maintain a balanced diet, in part because of our contemporary way of life. According to dietary studies, some micronutrients are not being consumed to their full potential in Europe. Inadequate intakes of vitamin C, vitamin D, folic acid, calcium, selenium, and iodine were found by the EURRECA project, which was supported by the EU. Recent comparisons of national surveys revealed broad concern with vitamin D levels, although inadequate mineral intakes are more common among some age groups. For instance, there are worries about teenage girls getting enough iron in Denmark, France, Poland, Germany, and the UK. 2 Young women with low iron levels are also more likely to have babies who are born with low birth weight, iron deficiency, and delayed brain development. 10 A woman's folate status is crucial if she plans to get pregnant. Folic acid supplementation is indicated both before and during the first 12 weeks of pregnancy. A newborn being born with neural tube defects like spina bifida is less likely to occur if the folate level is adequate. According to recent studies, the vitamin D level of 50–

70% of Europeans is subpar. There may be a better justification in Northern European nations for recommending vitamin D supplements because vitamin D status depends on both dietary consumption and UV exposure. Although there are calls for more research, there are currently recommendations for specific populations in various countries (such as the UK, Ireland, the Netherlands, and Sweden) to take a vitamin D supplement.

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